Serial No.: 09/772,790

Examiner S. Jiang; Group Art Unit 1617

tricosanol, tetracosanol, pentacosanol, hexacosanol, heptacosanol, octacosanol, nonacosanol, triacontanol, dotriacontanol, tetratriacontanol and hexatriacontanol.

- 2. The composition according to claim 1, wherein the acid moiety of the [ester and the] esters is a carboxylic acid containing from 2 to 22 carbon atoms.
- 3. The composition according to [claims 1 or] <u>claim</u> 2, further comprising [a food substance or a mixture of] <u>one or more</u> food substances.
- 4. The composition according to claim 3, wherein the food substance [or mixture of food substances] is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.
- 5. The composition according to claim [1 or] 2, further comprising a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 6. A method for lowering LDL-cholesterol level[s] or [for] elevating HDL-cholesterol level[s] in blood of a mammal [or both, which] ,wherein the method comprises orally administering to said mammal a composition comprising an effective amount of one or more [an] esters of a policosanol [or a mixture of esters of plicosanols] ,wherein the policosanol is selected from the group consisting of eicosanol, heneicosanol, docosanol, tricosanol, tetracosanol, pentacosanol, hexacosanol, heptacosanol, octacosanol, nonacosanol, triacontanol, dotriacontanol, tetratriacontanol and hexatriacontanol.
- 7. The method according to claim 6, wherein the acid moiety of the [ester and the] esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.
- 8. The method according to claim[s] 7, wherein the composition further comprises
  [a] one or more food substance [or a mixture of food substances].

Serial No.: 09/772,790

Examiner S. Jiang; Group Art Unit 1617

9. The method according to claim 8, wherein the food substance [o the mixture of food substances] is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.

- 10. The method according to claim 7, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 11. The method according to claim [9 or] 10, wherein the effective amount of [the] ester of the [policosanol or the mixture of the esters of the] policosanols [of] <u>in</u> the composition comprises a daily dosage from 1 to 500 mg of [said] <u>the</u> [ester or said mixture of] esters <u>of policosanol</u>.

Please add new claims 36 through 61.

- 36. The composition according to claim 2, wherein the carboxylic acid is selected from the group consisting of eicosapentaenoic acid, docosapentaenoic acid, linoleic acid, linoleic acid, linoleic acid and arachidonic acid.
- 37. The method according to claim 7, wherein the carboxylic acid is selected from the group consisting of eicosapentaenoic acid, docosapentaenoic acid, linoleic acid, linoleic acid, and arachidonic acid.
- 38. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of mammal, wherein the method comprises orally administering to said mammal an effective amount of the composition according to claim 1.
- 39. The method according to claim 38, wherein the acid moiety of the esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.

Serial No.: 09/772,790

Examiner S. Jiang; Group Art Unit 1617

40. The method according to claim 39, wherein the composition further comprises one or more food substance.

- 41. The method according to claim 40, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.
- 42. The method according to claim 39, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 43. The method according to claim 42, wherein the effective amount of ester of the policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of policosanol.
- 44. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of mammal, wherein the method comprises orally administering to said mammal an effective amount of the composition according to claim 4.
- 45. The method according to claim 44, wherein the acid moiety of the esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.
- 46. The method according to claim 45, wherein the composition further comprises one or more food substance.
- 47. The method according to claim 46, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.

Serial No.: 09/772,790

Examiner S. Jiang; Group Art Unit 1617

48. The method according to claim 45, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.

- 49. The method according to claim 48, wherein the effective amount of ester of the policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of policosanol.
- 50. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of mammal, wherein the method comprises orally administering to said mammal an effective amount of the composition according to claim 5.
- 51. The method according to claim 50, wherein the acid moiety of the esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.
- 52. The method according to claim 51, wherein the composition further comprises one or more food substance.
- 53. The method according to claim 52, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.
- 54. The method according to claim 51, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 55. The method according to claim 54, wherein the effective amount of ester of the policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of policosanol.

Serial No.: 09/772,790

Examiner S. Jiang; Group Art Unit 1617

<u>56.</u> A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of mammal, wherein the method comprises orally administering to said mammal an effective amount of the composition according to claim 36.

- 57. The method according to claim 56, wherein the acid moiety of the esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.
- 58. The method according to claim 57, wherein the composition further comprises one or more food substance.
- 59. The method according to claim 58, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.
- 60. The method according to claim 57, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 61. The method according to claim 60, wherein the effective amount of ester of the policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of policosanol.

A clean set of the claims is attached hereto as the Appendix.

## **ELECTION:**

The Examiner has required the Applicant to restrict the application to one of Groups I – VI, and further to elect a species. Applicant provisionally elects Groups I and II, subject to the traversal and request for reconsideration of the restrictions, as set forth below.

Examiner: Shaojia Jiang

Art Unit: 1617



AL

## APPENDIX A CLEAN SET

The following is a clean set of all remaining claims as they will stand in U.S. Application Serial No. 09/772,790 after entry of the Amendment dated January 16, 2003:

1. A composition for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of a mammal, wherein the composition comprises one or more esters of policosanol, wherein the policosanol is selected from the group consisting of eicosanol, heneicosanol, docosanol, tricosanol, tetracosanol, pentacosanol, hexacosanol, heptacosanol, octacosanol, nonacosanol, triacontanol, dotriacontanol, tetratriacontanol and hexatriacontanol.

- 2. The composition according to claim 1, wherein the acid moiety of the esters is a carboxylic acid containing from 2 to 22 carbon atoms.
- 3. The composition according to claim 2, further comprising one or more food substances.
- 4. The composition according to claim 3, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.
- 5. The composition according to claim 2, further comprising a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.
- 6. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of a mammal, wherein the method comprises orally administering to said mammal a composition comprising an effective amount of one or more esters of a policosanol, wherein the

Examiner: Shaojia Jiang

Art Unit: 1617

policosanol is selected from the group consisting of eicosanol, heneicosanol, docosanol, tricosanol, tetracosanol, pentacosanol, hexacosanol, heptacosanol, octacosanol, nonacosanol, triacontanol, dotriacontanol, tetratriacontanol and hexatriacontanol.

7. The method according to claim 6, wherein the acid moiety of the esters comprises a carboxylic acid containing from 2 to 22 carbon atoms.

8. The method according to claim 7, wherein the composition further comprises one or more food substance.

9. The method according to claim 8, wherein the food substance is selected from the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk and yogurt.

10. The method according to claim 7, wherein the composition further comprises a pharmaceutically acceptable component selected from the group consisting of an excipient, antioxidant, coloring agent, binder and stabilizer.

11. The method according to claim 10, wherein the effective amount of ester of the policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of policosanol.

36. The composition according to claim 2, wherein the carboxylic acid is selected from the group consisting of eicosapentaenoic acid, docosapentaenoic acid, linoleic acid, linoleic acid, linoleic acid and arachidonic acid.

37. The method according to claim 7, wherein the carboxylic acid is selected from the group consisting of eicosapentaenoic acid, docosapentaenoic acid, linoleic acid, linoleic acid, and arachidonic acid.

A1

AZ

Examiner: Shaojia Jiang

Art Unit: 1617

38. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level in blood of mammal, wherein the method comprises orally administering to said mammal an

39. The method according to claim 38, wherein the acid moiety of the esters

comprises a carboxylic acid containing from 2 to 22 carbon atoms.

effective amount of the composition according to claim 1.

40. The method according to claim 39, wherein the composition further comprises

one or more food substance.

41. The method according to claim 40, wherein the food substance is selected from

the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk

and yogurt.

42. The method according to claim 39, wherein the composition further comprises a

pharmaceutically acceptable component selected from the group consisting of an excipient,

antioxidant, coloring agent, binder and stabilizer.

43. The method according to claim 42, wherein the effective amount of ester of the

policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of

policosanol.

44. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level

in blood of mammal, wherein the method comprises orally administering to said mammal an

effective amount of the composition according to claim 4.

45. The method according to claim 44, wherein the acid-moiety of the esters

comprises a carboxylic acid containing from 2 to 22 carbon atoms.

3

Examiner: Shaojia Jiang

Art Unit: 1617

46. The method according to claim 45, wherein the composition further comprises

one or more food substance.

47. The method according to claim 46, wherein the food substance is selected from

the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk

and yogurt.

48. The method according to claim 45, wherein the composition further comprises a

pharmaceutically acceptable component selected from the group consisting of an excipient,

antioxidant, coloring agent, binder and stabilizer.

49. The method according to claim 48, wherein the effective amount of ester of the

policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of

policosanol.

50. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level

in blood of mammal, wherein the method comprises orally administering to said mammal an

effective amount of the composition according to claim 5.

51. The method according to claim 50, wherein the acid moiety of the esters

comprises a carboxylic acid containing from 2 to 22 carbon atoms.

52. The method according to claim 51, wherein the composition further comprises

one or more food substance.

53. The method according to claim 52, wherein the food substance is selected from

the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk

and yogurt.

4

Examiner: Shaojia Jiang Art Unit: 1617

54. The method according to claim 51, wherein the composition further comprises a

pharmaceutically acceptable component selected from the group consisting of an excipient,

antioxidant, coloring agent, binder and stabilizer.

55. The method according to claim 54, wherein the effective amount of ester of the

policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of

policosanol.

56. A method for lowering LDL-cholesterol level or elevating HDL-cholesterol level

in blood of mammal, wherein the method comprises orally administering to said mammal an

effective amount of the composition according to claim 36.

57. The method according to claim 56, wherein the acid moiety of the esters

comprises a carboxylic acid containing from 2 to 22 carbon atoms.

58. The method according to claim 57, wherein the composition further comprises

one or more food substance.

59. The method according to claim 58, wherein the food substance is selected from

the group consisting of table margarine, shortening, mayonnaise, vegetable oil, ice cream, milk

and yogurt.

60. The method according to claim 57, wherein the composition further comprises a

pharmaceutically acceptable component selected from the group consisting of an excipient,

antioxidant, coloring agent, binder and stabilizer.

61. The method according to claim 60, wherein the effective amount of ester of the

policosanols in the composition comprises a daily dosage from 1 to 500 mg of the esters of

policosanol.

5